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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,200	10/20/2003	Deana J. Dicosimo	CL1747USNA	8649

23906 7590 06/22/2005

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EXAMINER

VOGEL, NANCY S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/689,200	Applicant(s) DICOSIMO ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17, 18 and 20-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/14/04, 2/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group VII, claims 15, 16 and 19 in the reply filed on 3/30/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14, 17, 18, and 20-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/30/05.

Claim Objections

Claim 15 is objected to because of the following informalities: in part (a), the claim recites "selected from the group consisting of SEQ ID NO:2". Since applicants have cancelled the second member of the originally recited Markush group, (i.e. "and SSEQ ID NO:5), the claim no longer recites a group of alternative embodiments and is therefore objected to. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a nitrate inducible gene which is selected from the group consisting of an isolated nucleic acid molecule encoding the amino acid sequence shown in SEQ ID NO:2, and an isolated nucleic acid molecule that hybridizes with said nucleic acid encoding the amino acid sequence shown in SEQ ID NO:2 under stringent conditions and washing with 0.1X SSC, 0.1% SDS, 65°, or the complementary nucleic acid molecule, and which encodes a functional nitrate transporter (nrt transporter), does not reasonably provide enablement for a nucleic acid molecule encoding amino acid sequence shown in SEQ ID NO:2 which does not have this activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to an isolated nucleic acid molecule that hybridizes under stringent conditions and wash with 0.1X SSC, 0.1% SDS, 65° to a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2. There is no functional limitation in the claims.

Applicants have taught the nucleic acid molecule which encodes a nitrogen transporter whose sequence is disclosed in SEQ ID NO:2, as well as the promoter region thereof (SEQ ID

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NO:3). The specification discloses that the polypeptide whose sequence is shown in SEQ ID NO:2 is a nitrogen transporter.

The claim encompasses an unreasonable number of inoperative nucleic acid molecules, which the skilled artisan would not know how to use. While the specification teaches nucleic acids that encode a nitrogen transporter from the bacteria *Methylomonas*, no other function has been attributed to these molecules. Therefore, knowledge of these particular nucleotides and their function does not provide predictability of the function of structurally related variants having the ability to hybridize to said nucleic acid molecule under specified conditions.

There are no working examples of nucleotides other than those which are 100% identical to the particular sequences disclosed in the specification. The skilled artisan would not know how to use non-identical nucleic acids on the basis of teachings in the prior art or specification unless they possess the property of encoding a functional nitrogen transporter. The specification does not provide guidance for using nucleotides related to but not identical to the disclosed nucleotides. The claim is broad because it does not require the recited nucleotides to be identical to the disclosed sequences and because the claim has no functional limitation.

For these reasons, which include the unpredictability of the nature of the invention and art in terms of the lack of knowledge about the function(s) of encompassed nucleotides, the limited working examples using these nucleotides and their one function, the lack of direction or guidance for using nucleotides which are not identical to these nucleotides, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 is drawn in part to nucleic acid molecules that hybridize under specified conditions with an isolated nucleic acid molecule encoding the amino acid sequence consisting of SEQ ID NO:2. The claim does not require that the nucleic acid possess any particular biological activity, or that the polypeptide it encodes has any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claim is drawn to a genus of nucleic acids that is defined only by sequence identity. Furthermore, the claim is drawn to an isolated nucleic acid molecule encoding a nitrate inducible gene which is (a) an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2, or (b) an isolated nucleic acid molecule that hybridizes to (a) under stringent conditions. Since SEQ ID NO:2 discloses the amino acid sequence of a polypeptide, the nucleotide sequence of the promoter region which is nitrate inducible, which must be present for a gene to be nitrate inducible, is not identified. In regard to claim 16, the nucleic acid molecule set forth in SEQ ID NO:1 does not include a promoter region, and therefore the nitrate inducible promoter is not specified by nucleic acid sequence. Therefore, the claims encompass a genus of genes containing a promoter region which confers nitrate inducibility whose sequence is not recited.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of ability to hybridize to particular nucleic acid molecules under particular hybridization conditions, and a recitation that the gene is nitrate inducible. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids encoding the amino acid sequence of SEQ ID NO:2, under the control of the nitrate inducible promoter as disclosed in SEQ ID NO:3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

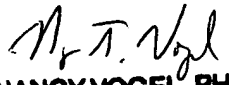
Claim 19 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NANCY VOGEL, PH.D.
PATENT EXAMINER